Basic Building Block Profile

Building Block: Patient Engagement vision

Vision

The Patient Engagement vision is defined by three core engagement areas:

Essential Engagement Services:

The starting point in the patient engagement journey, essential engagement services should provide a foundation of knowledge to support the other core engagement areas. Essential engagement tasks and services include:

- Consulting with patient engagement specialists, partners and services
- Working with patient support and advocacy groups to identify patient needs and desires
- Identification and active participation in patient communities
- Defining patient engagement evaluation criteria and metrics to engage with minimum burden
- Options and timing for return of data to the patient (patient and study)

Communication Engagement:

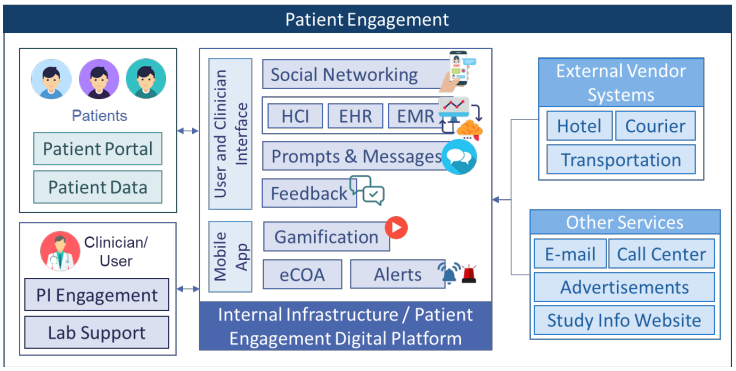
Taking knowledge from, and building on, the essential engagement services, communication engagement should define and include the most efficient and effective ways to communicate with our patients. Patient communication encompasses the bi-lateral sharing of information about the study itself, the planned interventions, general disease information, patient support resources, questionnaires, surveys and scales and logistics such as medication tracking.
Methods of communication engagement may include:
Central patient portal / environment / website / app(s)
Videos, digital leaflets and newsletters
Visit schedule / calendar downloads and syncing, visit alerts
Patient communities and outreach
Chat rooms, wikis, blogs, advocacy group links/FAQs
eCOA communication services e.g. compliance metrics/feedback, satisfaction surveys, reminders
Conversational AI and (digital) patient concierge services

Motivation Engagement

Motivating our patients to maintain engagement momentum is key to both patient adherence and successful study completion. Motivation engagement should include several methods including:
Provision of study devices such as wearables, monitors, digital health sensors etc
Mobile apps with potential for gamification / achievement tracking and sharing
Thanks and acknowledgments
Expense reimbursements where appropriate
Relevant and timely return of patient data to the patient via summaries, reports, achievements etc

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Activities



Included activities in the RFP:

The following activities are included in the RFP:

- **Patient / study data return** - method of providing individual patient data back to the patient in a way that engages, empowers, provides insight into patient's personal health / disease state or progression etc.
    - Visuals, text, awards, recognitions
- **Engagement consulting services** - digital engagement program for duration of study
- **Social Media capabilites** - program for duration of study
- **Conversational AI**

Excluded activities from the RFP:

The activities below are already covered by internal partner and **excluded from the RFP**:

- Central patient portals / apps
- APIs, integrations, interoperabiltiies
- Calandar, schedule, visit management
- ECOA
- Patient concierge
- Device independence
- Messaging, rewards, thanks, achievements etc
- Compliance
- Clinical monitoring

Functional Requirements

Essential Engagement Services:

- Social media expertise with relevant advocacy groups, patient communities
- Ability to host, aggregate, consolidate, update and display patient's personal health data inaccordance with security and privacy requirements (safety/privacy, GDPR-compliant)
- Ability to request expense reimbursements where appropriate
- Relevant and timely return of patient data to the patient via summaries, reports, achievements etc
- Ability to host, aggregate, consolidate, update and display patient's personal health data inaccordance with security and privacy requirements (safety/privacy, GDPR-compliant)

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Additional Non-Core Services:

- Conversational AI and/or chat-bot services through central portal and/or patient's own smart devices (Alexa, Bixby)

Technical requirements

1. Readily available APIs to enable integration / interoperability / single sign-on features
2. Device independence:
    - Can be accessed / run by both android and iOS fixed and mobile devices and operating systems
    - Support for all common browsers and browser release versions
    - Available and can be synced with desktop URL site
    - Can be used with incumbent smart devices such as Alexa, Bixby etc
3. Any companion apps, wearables and medical devices - if applicable - should allow:
    - Sufficient battery life with ease of recharge
    - Lightweight, unobtrusive/discreet design
    - Relevant safety certifications, documentation
    - FDA device classification and/or CE approval (and covering any companion mobile apps)
4. Compliance with:
    - GxP regulatory requirements
    - GDPR / Privacy requirements
    - 21CFR11 / EU CTR / ICH GCP

RFP – Knockout Criteria:

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

Patient / study data return

The technology will be rejected if:

1. Not compatible with any/all mobile devices
2. Not compatible with any/all browsers (latest version + previous still-supported common versions)
3. Language limitations

Engagement consulting services

The technology will be rejected if:

1. Inexperience in Diabetes TA

Social Media capabilites

The technology will be rejected if:

1. Inexperience in Diabetes TA

Conversational AI

The technology will be rejected if:

1. Not compatible with any/all devices
2. Not compatible with any/all browsers (latest version + previous still-supported common versions)
3. Language limitations
4. POC / infant product

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